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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,487	08/18/1999	AWADHESH K. MISHRA	28069-504	6585
35437	7590	04/08/2005	EXAMINER	
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO 666 THIRD AVENUE NEW YORK, NY 10017			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/376,487

Applicant(s)

MISHRA ET AL.

Examiner

Edward J. Webman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) ☒ Claim(s) 45-61, 63-67, 69-78, 80, 81, 87-93, 96, 99-122, 125, 128-135, 137 and 139-160 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☒ Claim(s) 45-55, 77, 78, 80, 81, 87-93, 96, 99-105, 137, 139-150 and 160 is/are allowed.

6) ☒ Claim(s) 56--61, 63-67, 69-76, 106-122, 125, 128-135, 151-159 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/14/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56-61, 63-67, 69-76, 106-122, 125, 128-135, 153-159 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 770387 (EPA '387) in view of Harrison and Shaw et al.

EPA '387 teaches a composition comprising 0.1-2% central acting anesthetic, 5-30% long chain and/or medium chain triglycerides, and 0.5-2% emulsifier (abstract). Olive oil is disclosed (column 3 line 34). Lecithin is specified (column 3 line 48). A ratio of 10:1-1:10 long to medium chain triglycerides is specified (column 3 lines 49-50). Mannitol is disclosed as a tonicity agent (column 4 line 26). A droplet size of 0.2-0.35  $\mu$ m is specified (column 5 line 2). Long term stable emulsions are disclosed (column 3 line 9).

The examiner takes notice under MPEP 2144.03 that propofol is well-known in the art as a central acting anesthetic.

It would have been obvious to one of ordinary skill to deliver propofol, well-known in the art as a central acting anesthetic, in the vehicle of EPA '387 to achieve the beneficial effect of long term stability. As to the claimed mannitol concentration, Harrison teaches up to 5 % (column 2 lines 48-53) as a tonicity agent. Thus, it would have been obvious to one of ordinary skill to use up to 5% mannitol in the vehicle of EPA'387 to achieve the beneficial effect of a tonicity agent. As to the claimed viscosity,

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Shaw et al teach that mannitol is well-known in the art as a thickener (column 4 lines 11-14), so that an increase in viscosity would be expected. It is argued that the claimed viscosity would follow from the percent mannitol taught by Harrison.

Claims 151-159 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.


In claims 151(b), 152(b) and 153(b), "up to" includes zero. It is unclear as to whether applicants intend to claim 0% diluent.

Claims 56-61, 63-67, 69-76, 106-122, 125, 128-135, 151-159 rejected.

Claims 45-55, 77, 78, 80, 81, 87-93, 96, 99-105, 137, 139-150, 160 are allowed.

Any inquiry concerning this communication should be directed to Edward J.

Webman at telephone number 571-272-0633.



EDWARD J. WESMAN  
PRIMARY EXAMINER  
GROUP 1500